

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 16 NOV 2005

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To:
MARK A. CATAN
PROSKAUER ROSE LLP
1585 BROADWAY
NEW YORK, NY 10036

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **14 NOV 2005**

Applicant's or agent's file reference

53951-137

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/36933

International filing date (day/month/year)

05 November 2004 (05.11.2004)

Priority date (day/month/year)

04 January 2002 (04.01.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61M 37-00, A61M 1/00 and US Cl.: 604/6.1, 6.01, 4.01, 34, 210/424, 137/625.43

Applicant

NXSTAGE MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Date of completion of this
opinion

01 September 2005 (01.09.2005)

Authorized officer

Leslie R. Deak

MONICA A. GRAVES

Telephone No. 571-272-2975

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/36933

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/36933

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Industrial applicability (IA)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-15 lack an inventive step under PCT Article 33(3) as being obvious over US 6,308,737 to Kritiviski. Kritiviski discloses a deformable diverter 80 that serves as a valve body with four ports 100, 200, 300, and 400. Portions of the interior surface of the diverter are selectively contacted through a pinching deformation to isolate ports from one another, creating a flow channel between the two selected ports (see columns 5-7). The ports are configured to be attached to tubing lines 52, 54, 56, and 58 (see FIG 7). According to the illustration in FIG 14, the cross-sectional area between port 300 and port 400 remains substantially constant. With regard to applicant's claim that the valve body is toroidal in shape, the diverter of the Kritiviski device is comprised of an outer and inner surface with a common, empty chamber within the surfaces, rendering the diverter toroidal, with an empty space in the middle, in shape. Nonetheless, absent a showing of the criticality of the cross-sectional area or the toroidal shape to the function of the device, a change in size of a component involves only routine skill in the art. A change in form or shape is generally recognized as being within the level of ordinary skill in the art.

With regard to applicant's claim that the flow channel is cylindrical in cross-section, it would have been an obvious matter of design choice to design the Kritiviski diverter to create a cylindrical cross-section since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art.

With regard to applicant's claims drawn to the tubular portions being pinched of during use, the Kritiviski device does comprise tubular portions in the form of the ports of the diverter. The diverter is pinched in a manner that allows these tubular portions to communicate with or be isolated from one another, depending on the configuration. Applicant's recitation that the tubular portions are pinched during operation of the device amounts to a recitation of the intended use of the invention. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

Claims 1-15 meet the criteria set out in PCT Article 33(4), and thus satisfy industrial applicability because the subject matter claimed can be made or used in industry.